UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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JESSE MCDOWELL,

Plaintiff,

13 Civ. 3786

-against-

OPINION

ELI LILLY AND COMPANY,

Defendant.

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A P P E A R A N C E S:

Attorneys for Plaintiff

POGUST BRASLOW & MILLROOD LLC
Either Tower Bridge
161 Washington Street, Suite 1520
Conshohocken, PA 19428

By: Harris L. Pogust, Esq.

Attorneys for Defendant

COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956

By: Michael X. Imbroscio, Esq.
Phyllis A. Jones, Esq.
Brett C. Reynolds, Esq.

Sweet, D.J.

Plaintiff Jesse McDowell ("McDowell" or "Plaintiff") has moved pursuant to Local Rule 6.3 and Federal Rule of Civil Procedure 59(e) for reconsideration of the grant of summary judgment on November 7, 2014 (Dkt No. 34) dismissing McDowell's complaint (the "November 7 Order"), alleging product liability arising out of his use of Cymbalta, a drug produced by the Defendant Eli Lilly and Company ("Eli Lilly" or the "Defendant"). McDowell has also moved to supplement the record and to file certain material under seal. Based on the conclusions set forth below, the motion for reconsideration is denied. The motion of McDowell to supplement the record on this motion and to file materials under seal is granted.

Prior Proceedings

McDowell filed suit against Eli Lilly on June 4, 2013 alleging product liability arising out of the use of Eli Lilly drug Cymbalta. Following a scheduling conference, an order was entered an order providing for two discovery phases: "Core Case-Specific Discovery," which encompassed the IND/NDA files for Cymbalta (over 1.8 million pages); McDowell's medical records; and the depositions of McDowell and his medical providers, and,

if necessary after summary judgment briefing, "Non-Core Discovery." (See Dkt. No. 8.) The order provided that summary judgment motions would be filed on "Core Case-Specific Discovery issues" within thirty days of the specified depositions. (Id.) Eli Lilly filed its motion for summary judgment on the grounds of adequacy and proximate cause on July 7, 2014. Briefing was completed on this motion with Eli Lilly's Reply on August 22, 2014. Oral argument was held on September 17, 2014 and the November 7 Order was entered granting Eli Lilly's motion for summary judgment, dismissing the complaint.

On September 22, 2014, McDowell's counsel here submitted expert reports by Dr. Joseph Glenmullen and Dr. Louis Morris on behalf of its clients in two other Cymbalta cases, Herrera v. Eli Lilly & Co., Inc. and Hexum v. Eli Lilly & Co., Inc., which are currently pending in the Central District of California.

Prior to this Court's ruling, McDowell was also one of a group of plaintiffs who sought before the Judicial Panel on Multidistrict Litigation ("JPML") to centralize related Cymbalta actions for coordinated pre-trial proceedings. The JPML denied the motion to centralize on December 10, 2014.

McDowell seeks reconsideration of the grant of summary judgment and to supplement the record with the two expert reports of Dr. Glenmullen and Dr. Morris, the Cymbalta European Summary of Product Characteristics, and the JPML petition. McDowell also seeks to file under seal an internal Eli Lilly memorandum ("Internal Memorandum") produced in the Hexum litigation after Plaintiff's motion for reconsideration was filed.

The motions for reconsideration and to supplement the record were marked fully submitted on December 17, 2014. Plaintiff's motion to file the Internal Memorandum under seal was marked fully submitted on January 6, 2015.

The Applicable Standard

Under Federal Rule of Civil Procedure 59(e) and Local Civil Rule 6.3, a party seeking reconsideration must "demonstrate controlling law or factual matters put before the court on the underlying motion that the movant believes the court overlooked and that might reasonably be expected to alter the court's decision." MBIA Ins. Corp. v. Patriarch Partners VIII, LLC, 842 F. Supp. 2d 682, 715 (S.D.N.Y. 2012). As the Second Circuit has stated, and this Court has reiterated on

numerous occasions, motions for reconsideration "are not vehicles for taking a second bite at the apple . . . and [the court] [should] not consider facts not in the record to be facts that the court overlooked." Id. at 716 (quoting Rafter v. Liddle, 288 F. App'x 768, 769 (2d Cir. 2008)) (alterations in original) (internal quotation marks omitted).

Reconsideration of a court's prior order is an "extraordinary remedy to be employed sparingly in the interests of finality and conservation of scarce judicial resources." Sikhs for Justice v. Nath, 893 F. Supp. 2d 598, 605 (S.D.N.Y. 2012) (citations omitted). Accordingly, the rule must be strictly and narrowly construed to avoid "duplicative rulings on previously considered issues," id., and to "prevent the practice of a losing party examining a decision and then plugging the gaps of a lost motion with additional matters." Jackson v. Odenat, 9 F. Supp. 3d 342, 368 (S.D.N.Y. 2014) (quoting Grand Crossing, L.P. v. U.S. Underwriters Ins. Co., No. 03-cv-5429, 2008 WL 4525400, at *3 (S.D.N.Y. Oct. 6, 2008)) (internal quotation marks omitted); see also Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995).

The New Evidence Does Not Require Reconsideration

McDowell asserts, simply because an expert discovery deadline was not explicitly identified in the Court's scheduling order, that he was unable to include expert reports to demonstrate issues of material fact. There is no basis for this limitation. (See Dkt. No. 8.) If McDowell had fundamental objections to the scheduling order set by the Court, his remedies were to move to amend the order or — as he himself identifies (see Mot. to Reconsider 4) — to oppose Eli Lilly's motion under Rule 56(d) and seek additional discovery. If the expert reports truly represented a new discovery as of their filing date, September 22, McDowell could have moved even then to supplement his opposition and put them before the Court. The fact that Plaintiff chose not to take these actions because he believed the testimony of the prescribing nurse practitioner, Joan Caruana ("Caruana") "was independently sufficient to establish genuine issues of material fact," and he did not "expect[] to need more" to contest summary judgment, does not constitute a compelling reason to grant the reconsideration motion. (Mot. to Reconsider 4.)

Neither expert report that McDowell has now produced cites any non-public sources or any material (aside from other

expert reports) that post-date the briefing in this case. (See Glenmullen Report 42-50, Ex. 2; Morris Report Attachment B.) Unlike cases in which new facts "come to light" that warrant reconsideration, see In re Bear Stearns Cos. Inc. Sec., Derivative, & ERISA Litig., 2011 WL 4357166, at *3 (quoting Harris v. Amgen, Inc., 573 F.3d 728, 737 (9th Cir. 2009)), here there is no new factual basis for the expert report of either Dr. Glenmullen or Dr. Morris.

McDowell's motion refers to Dr. Morris's reliance on a report by the Institute for Safe Medication Practices ("ISMP") and the European Summary of Product Characteristics. (See Mot. for Reconsideration 8-9.) However, the complaint itself features the ISMP report dated October 3, 2012 and McDowell relied upon it in his original opposition. (See Compl. ¶¶ 25-29; Pls.' Opp'n to Def.'s Mot. for Summ. J. 3.) Moreover, the relevant text in the European labeling has been in place and publicly available since May 2006. See European Medicines Agency, Cymbalta: Procedural steps taken and scientific information after the authorization, at 18, available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000572/WC500036807.pdf ("31/05/2006 . . . In this variation warnings have been included in section 4.4 of the SPC:

. . . to update information on withdrawal syndrome seen on discontinuation of treatment."). Finally, McDowell presented the European label to the Court at oral argument, reflecting counsel's awareness of the European labeling well before this Court's decision.

Substantively, McDowell's expert reports serve only to repeat the arguments that were presented.

McDowell has cited Dr. Glenmullen's report as demonstrating that based on the figures put forth in the 2005 Perahia article, the Cymbalta label does not accurately characterize either the frequency or severity of discontinuation-emergent adverse events. (See Mot. to Reconsider 5-6.) This was the express theory of McDowell's complaint (Compl. ¶¶ 13-20) and the precise point made by McDowell's opposition to Eli Lilly's original motion: "[Eli Lilly] withheld the accurate figures regarding severity and frequency of withdrawal symptoms while offering a much, much milder statistic in its stead." (Pl.'s Opp'n to Def.'s Mot. for Summ. J. at 7.) The alleged discrepancies between the discussion of discontinuation symptoms in the label and the results of the 2005 Perahia study were considered and it was concluded that, as a matter of law, the label properly

characterized the risks. (See November 7 Order at 37-38) ("Using a numerical threshold for the inclusion of adverse events in a label is an appropriate, standard methodology for identifying adverse events arising with sufficient frequency to warrant inclusion in the product label.").) The report by a retained expert does not constitute "new evidence" meeting the high standard warranting reconsideration. See, e.g., Becnel v. Deutsche Bank AG, 838 F. Supp. 2d 168, 171 n. 21 (S.D.N.Y. 2011) (finding that an expert report could not "rescue [Plaintiff's] case" and noting that "While no court in this district has explicitly addressed whether these kinds of expert reports qualify as newly discovered evidence in the civil context, courts in other circuits have held that they do not) (citations omitted); see also Ames v. Apothecon, Inc., 431 F. Supp. 2d 566, 571 (D. Md. 2006) (granting summary judgment despite dueling expert reports: "The debate between the experts need not be resolved by the jury. Dr. Blume does not dispute the aspect of Dr. Stern's testimony that is critical to the application of the learned intermediary doctrine.").

McDowell contends that Dr. Glenmullen's report requires reconsideration because it undermines the Court's determination that the questioning of Caruana about the relative discontinuation profiles of Cymbalta and Effexor was

inadmissible for lack of foundation. (See Mot. to Reconsider 6-7 (citing Glenmullen Report at 17-19 & tbl. 6).) However, the ruling on this point was a "separate, stand-alone ground for rejecting [Caruana's testimony about Effexor] as a basis for denying summary judgment." (November 7 Order at 50.) The Court held that McDowell failed to prove proximate cause on several other grounds — (a) that Caruana was independently aware of the risk of discontinuation (id. at 40-44) and (b) that Caruana would not have changed her prescribing decision if the warning contained information that discontinuation occurred in 40 to 50 percent of patients (id. at 45-48) — the admissibility of this particular testimony would be insufficient to change the Court's ruling on proximate cause. As the Court's decision would not be altered, reconsideration is unwarranted. MBIA Ins. Corp., 842 F. Supp. 2d at 715.

In addition, Dr. Glenmullen's expert report cannot be used to cure the lack of foundation in Plaintiff's counsel's questioning. Federal Rule of Evidence 602 states that a lay witness, like Caruana, "may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter." Similarly, a lay witness may offer opinion testimony only if it is, among other criteria, "rationally based on the witness's perception." Fed. R. Evid.

701. Not only did Caruana have no personal knowledge of the question put to her by Plaintiff's counsel – that "Cymbalta was worse" than Effexor with respect to withdrawal (see November 7 Order at 50; Caruana Dep. at 122:7-24) – her personal knowledge was the opposite. She testified, as was noted, that Cymbalta's discontinuation effects were "not as severe as those experienced upon abrupt withdrawal from Effexor." (November 7 Order at 49 (citing Caruana Dep. at 68:10-13, 70:18-71:2).)

Finally, Dr. Glenmullen's report does not state that the discontinuation profiles of Effexor and Cymbalta are equivalent or that Cymbalta is "worse," as counsel's question to Caruana hypothesized. Dr. Glenmullen's report identifies the half-life and elimination time of a drug as significant to its discontinuation profile and states that Effexor's half-life is 5 hours with 90% of the drug eliminated in 1 day, while Cymbalta's half-life is 12 hours with 90% of the drug eliminated in 2.5 days. (See Glenmullen Report at 19 tbl. 6.) Dr. Glenmullen also points out that 78% of Effexor patients experience discontinuation symptoms, and that he would expect a smaller percentage of Cymbalta patients to experience those symptoms because it has a longer half-life. (See id. at 18.) As a result, the report does not support McDowell's questioning to

Caruana and does not provide a basis for reconsidering the summary judgment ruling.

Dr. Morris's report likewise does not present new factual matters that were overlooked and are likely to alter the summary judgment decision. Dr. Morris, a social psychologist, not a medical doctor (see Morris Report at 1) states, as McDowell has continued to argue, that the phrase "1% or greater" in the label is misleading to medical professionals in the context in which it appears (see Morris Report at 10) based on his reading of the language of the label itself. (See id. (explaining how "a reader would interpret the phrase" without citation).) However, it has already been found, based upon her undisputed testimony, that Caruana, an experienced medical professional who has frequently prescribed antidepressants like Cymbalta, was not misled by the language in question, and that the plain language of the warning properly describes the risks alleged. (See generally November 7 Order.) Although McDowell argues the adequacy of Eli Lilly's warning in light of FDA's regulations and guidances, Dr. Morris' report does not rely on or analyze any of those sources. Dr. Morris' opinion therefore adds nothing in the face of the warning's plain language and Caruana's undisputed testimony about how she understood that language.

Dr. Morris' review of the ISMP report and the Cymbalta SmPC likewise adds nothing to the analysis of the adequacy of Cymbalta's warning. As discussed above, McDowell cited the ISMP report both in his complaint and in his opposition to Eli Lilly's motion for summary judgment for the proposition that there is a 44-50% rate of discontinuation symptoms in Cymbalta patients, and counsel even attached it as an exhibit. (See Pl.'s Opp'n to Def.'s Mot. for Summ. J. 4; Pogust Decl., Ex. 5 (Dkt. 27-5).) Dr. Morris' report does not perform any actual analysis of the ISMP report that would add to this Court's consideration of the report itself but summarizes the allegations. (See Morris Report at 11-12.) Dr. Morris' review of the SmPC summarizes its contents and notes that it is "quite different" from the U.S. label.

The mere existence of a differently structured and written European label does not establish that the U.S. label is insufficient, misleading, or legally inadequate, nor is foreign regulatory action even appropriate as a subject of expert testimony in pharmaceutical cases. See, e.g., In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d. 531, 553 (S.D.N.Y. 2004) ("[T]he challenged testimony focuses on a set of non-technical factual allegations - specifically, the actions taken or not taken by foreign regulators or Glaxo-Wellcome with respect to

Rezulin - that plaintiffs would use as springboards for arguments about Warner-Lambert's conduct in the United States. None of it qualifies as 'scientific, technical or other specialized knowledge.'") (citations omitted); Lofton v. McNeil Consumer & Specialty Pharms., Civil Action No. 3:05-CV-1531-L (BH), 2008 WL 4878066, at *6 (N.D. Tex. July 25, 2008) (excluding under Daubert expert labeling opinion discussing in part difference between American and European labels), aff'd, 682 F. Supp. 2d 662 (N.D. Tex. 2010), aff'd, 672 F.3d 372 (5th Cir. 2012).

Additionally, McDowell alleges his petition before the JPML to transfer a set of actions for coordinated pretrial proceedings constitutes new evidence. The denial of the petition moots the contention.

Controlling Decisions Were Not Overlooked

Procedurally, as noted above, reconsideration requires that the movant demonstrate that the Court overlooked controlling decisions or material facts that were before it on the original motion. Anglo Am. Ins. Group v. CalFed, Inc., 940 F. Supp. 554, 557 (S.D.N.Y. 1996) (citations omitted). "Controlling decisions include decisions from the United States

Court of Appeals for the Second Circuit; they do not include decisions from other circuits or district courts, even courts in the Southern District of New York." Heffernan v. Straub, 655 F. Supp. 2d 378, 380-81 (S.D.N.Y 2009). McDowell has not specified any controlling legal decisions that were overlooked; rather, he disagrees with the application of the relevant legal standards and reliance on other, similar cases. Moreover, his argument regarding the Court's interpretation of Caruana's testimony is precisely the same as the one presented to the summary judgment motion. He has provided no legal authority that requires the Court to alter its decision, and thus fails to demonstrate that reconsideration is warranted. See In re Bear Sterns, 2014 WL 4443458, at *3 (S.D.N.Y. Sept. 9, 2014).

McDowell's position continues to rest on an interpretation of Caruana's testimony that was rejected and was contrary her deposition. Caruana was asked to assume — contrary to her own experience — that she had been given information that Cymbalta was as bad or worse than Effexor. (Caruana Dep. at 122:7-24.) A response to a false hypothetical is insufficient to surmount the standard for summary judgment in the face of straightforward testimony on the part of Caruana that the inclusion in the Cymbalta package insert of the "44.3%" figure would have had no impact on her decision to use Cymbalta. (Id.

at 57:20-58:11.) Moreover, the absence of any basis in the record for this hypothetical was sufficient reason to exclude it. Plaintiffs in pharmaceutical cases may ask doctors what they would have done in the face of a stronger warning, see Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 285-86 (S.D.N.Y. 2009), but that hypothetical stronger warning must have a factual basis. See Boehm v. Eli Lilly & Co., 747 F.3d 501 (8th Cir. 2014) (affirming summary judgment where prescribing doctor was given scientifically unsupported hypothetical about alternative warning).

McDowell further objects to the Court's application of Gurski v. Wyeth-Ayerst Div. of Amer. Home Prods. Corp., 986 F. Supp. 654 (D. Mass. 1997), and Alston. He notes that in the Gurski case, both sides submitted expert testimony that agreed that the warnings were adequate, which is distinct from the case at hand. (See Mot. to Reconsider 15.) Although this observation is true, it is also irrelevant. Gurski sets forth a useful enunciation of the standard for the adequacy of a pharmaceutical label, for which the Court cited the case. (See November 7 Order.) The standard itself is unaffected by the depth of the evidentiary record in the case, and the case may nonetheless serve as persuasive guidance for when summary judgment is appropriate.

McDowell argues that the Alston case is inapposite because the plaintiff there made no arguments about the relative frequencies of the adverse events at issue. (See Mot. to Reconsider 15-16.) Like Gurski, Alston enunciates and applies the standard for the adequacy of a pharmaceutical warning: in New York, "that prescription medicine warnings are adequate when, as here, information regarding 'the precise malady incurred' was communicated in the prescribing information." Alston, 670 F. Supp. 2d at 284 (quoting Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 60, 423 N.Y.S.2d 95, 96 (4th Dep't 1979) aff'd, 52 N.Y.2d 768, 417 N.E.2d 1002 (1980)). Alston demonstrates that the precise frequency of particular events need not be included in a pharmaceutical warning to render it adequate.

The testimony in the record established that the experienced prescriber of McDowell's medication was not misled. (See November 7 Order at 38.) No controlling decisions are established as having been over looked.

Manifest Injustice Has Not Been Established

McDowell claims that the Court's ruling renders a "manifest injustice" to him and to his fellow MDL petitioners.

However, he has in no way demonstrated that the decision was "dead wrong" or that "extraordinary circumstances" are present. Oceangate Transp. Co. Ltd. v. RP Logistics Pvt. Ltd., No. 06 Civ. 9441, 2007 WL 2900225, at *1 & n.1 (Oct. 4, 2007); see also In re Bear Stearns, 2014 WL 4443458, at *6 ("Cohen's current position represents a disagreement with the Opinion with no proffered legal basis to conclude that the decision was 'wrong' rather than a showing of 'manifest injustice.' Consequently, reconsideration is inappropriate."). The decision does not work a "manifest injustice" upon persons not party to this action. The ruling will not estop non-party plaintiffs from contesting the point. No injustice has been established.

Conclusion

For the foregoing reasons, the motion of McDowell to reconsider the Court's summary judgment ruling is denied. Plaintiff's motion to supplement the record on this motion and to submit the Internal Memorandum under seal is granted.

With respect to the Internal Memorandum, that document will not now be addressed but may be the subject of a further motion to reconsider.

It is so ordered.

New York, NY
February 25, 2015

ROBERT W. SWEET
U.S.D.J.